

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: <i>All Wave 4 cases listed in Exhibit A to Defendants' Motion</i>	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO
DEFENDANTS' MOTION TO EXCLUDE DR. SUZANNE PARISIAN, M.D.**

Plaintiffs respectfully submit this Memorandum of Law in Opposition to Defendants Ethicon, Inc. and Johnson & Johnson's ("Defendants'") Motion to Exclude Dr. Suzanne Parisian, M.D.

Introduction and Qualifications of Dr. Suzanne Parisian

Dr. Parisian is a medical doctor, pathologist, and regulatory expert who has served as a regulatory and medical consultant since 1995. Dr. Parisian was an FDA employee. Dr. Parisian has over twenty-four years of experience in developing medical devices and began her career as a physician in 1980. Dr. Parisian served as a commissioned officer in the United States Public Health Service, where she was assigned as a medical officer to the FDA's Center for Devices and Radiological Health ("CDRH"). During this period, Dr. Parisian's duties included both pre-market and post-market review and monitoring of issues related to medical devices. (Def. Exhibit D at 6-7). Both in her position as an FDA employee and in her consulting business, Dr. Parisian reviewed hundreds of marketing applications and draft labeling for a conglomeration of medical devices. (*Id.* at 8). Additionally, she has been involved with product design and

submissions for approval or clearance to the FDA. In total, Dr. Parisian is eminently qualified to render her opinions because she has decades of experience working with pharmaceutical and medical devices.

Legal Standard

The task of evaluating the reliability of expert testimony is uniquely entrusted to the district court. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 589 (1993). District courts enjoy “considerable leeway” in determining the admissibility of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Under Federal Rule of Evidence 702, if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, provided the testimony (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” (3) which have been reliably applied “to the facts of the case.” *See Tyree*, 54 F. Supp. 501, 515-16 (S.D. W. Va. 2014); *see also In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 601 (S.D. W. Va. 2013). A two-part test governs the admissibility of expert testimony (and is combined with Rule 702’s qualification standard). *See* Rule 702; *see also Tyree*, 54 F. Supp. at 515-16. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597; *see also Tyree*, 54 F. Supp. at 516.

The proponent of expert testimony does not have the burden to “prove” anything. He must, however, “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998); *Tyree*, 54 F. Supp. at 516. All *Daubert* demands is that the trial judge serve as a gatekeeper and make a “preliminary assessment” of whether the proffered testimony is

both reliable and helpful. *Tyree*, 54 F. Supp. at 516. In making the required preliminary assessment, the trial court ““need not determine that the proffered expert testimony is irrefutable or certainly correct”” because, as with all testimony, it will be subject to “testing” by cross-examination, contrary evidence, and instruction on the burden of proof. *See Id.* (quoting *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006)).

The applicable law requires that Rule 702 be applied flexibly, *see Daubert*, 509 U.S. at 594, so as to uphold the general framework of the Rules, which favors the admissibility of evidence over non-admissibility. *Id.* at 588; *see also Tyree*, 54 F. Supp. at 516. In short, “the rejection of expert testimony is the exception rather than the rule.” *United States v. Stanley*, No. 12-4572, 2013 WL 3770713, at *1 (4th Cir. July 19, 2013) (internal quotations omitted).

Argument

This Court has twice ruled that Dr. Parisian is qualified to testify in a number of different areas.¹ Despite these favorable rulings regarding Dr. Parisian’s testimony, Ethicon again asserts challenges to Dr. Parisian’s testimony that are nearly identical to those asserted previously. Rather than addressing the substance of Dr. Parisian’s opinions, Ethicon again attempts to obfuscate the Court’s inquiry by presenting to the Court a haphazard conglomeration of cases where Dr. Parisian’s opinions were limited, often only in part, to support sweeping and generalized arguments to exclude Dr. Parisian’s opinions. These opinions, involving different cases and different facts, have minimal relevance to the Court’s inquiry *in this case*. In fact, Defendants again fail to account for the fact that Dr. Parisian has been allowed to testify in TV mesh state courts actions, and, in fact, proffered testimony in at least one TV mesh trial, *Barba v.*

¹ *In re: Ethicon Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2016 WL 4608165 (S.D. W. Va. Sept 2, 2016); *In re: Ethicon Pelvic Repair Sys. Prod. Liab. Litig.*, MDL 2327, 2017 WL 1268790 (S.D. W. Va. March 29, 2017).

Boston Scientific. (See Trial Trans. (5/18/2015) at 21:4-23:12; 26:11-98:17, attached as Ex. A, *Barba v. Boston Scientific*, C.A. No. N11c-08-050 (Del. Sup. Ct.)). In that matter, the Court found Dr. Parisian's opinions relevant and reliable to testify concerning the FDA's regulatory process, the 510(k) clearance process, Boston Scientific's actions within that process, and Boston Scientific's labeling.

Defendants again argue against opinions that Dr. Parisian does not offer, including opinions that Dr. Parisian overtly states she **will not** offer, in an attempt to conclude that Dr. Parisian has exceeded the bounds of her expertise. The Court should reject these baseless arguments. Defendants fail to confront the reality of Dr. Parisian's report. The only relevant inquiry is the reliability and relevance of Dr. Parisian's opinions on the Prolift+M and TVT-S, not the illusory opinions that Dr. Parisian does not offer or seek to present at trial. Of note, Defendants' memorandum challenging Dr. Parisian's opinions in Wave 4 is nearly identical to their memorandum challenging her opinions in Wave 3, with two notable additions: (1), Defendants Cite a newly issued opinion, *Rheinfrank v. Abbott Labs., Inc.*, Case No. 16-3347, 2017 WL 680349 (6th Cir. Feb. 21, 2017), an extremely narrow ruling wholly distinguishable from the facts of this case for the proposition that Dr. Parisian is not qualified to offer any opinions on scientific topics, and (2), a request that Dr. Parisian not be permitted to opine as to any product as to which she has not prepared an expert report, which is conceded. Dr. Parisian does not intend to offer any opinions regarding products other than the TVT-S and Prolift +M at this time. Accordingly, Plaintiffs' response to Defendants' Wave 4 motion is also nearly identical to Plaintiffs' response in Wave 3, with the exception of addressing the *Rheinfrank* rulings. See Defendants' Memorandum in Support to Exclude Dr. Parisian, ECF No. 2843 [Wave 3]. Moreover, the district court's ruling in *Rheinfrank* also bolsters the legal support and

precedent for Dr. Parisian to testify that Ethicon's communication of safety risks to physicians was inadequate, and to opine as to what actions Ethicon could have taken and/or was required to take with respect to communicating risks to healthcare professionals. *See Rheinfrank v. Abbott Labs.*, Case No. 13-cv-144-SJD (S.D. Ohio), Order Ruling on *Daubert* Motions (ECF No. 298), at 15, Defendants Exhibit C.

I. Dr. Parisian Is Qualified To Offer The Opinions Set Forth In Her Reports.

Defendants first argue that Dr. Parisian is not qualified to offer any opinions on issues such as medical causation or any other scientific topics. Dr. Parisian has already explicitly stated and conceded, in her reports, that she does not intend to offer any medical causation opinions or standard of care for treating physicians opinions. (Def. Ex. D at ¶ 14, 23, Def. Ex. E at ¶14, 23). Dr. Parisian has also conceded, during her deposition, that she will not offer any opinions about manufacturing defect issues. (Def. Ex. F at 48:3-49:16). However, Defendants attempt to expand these concessions into a vague, self-created category of "other scientific topics" to challenge Dr. Parisian's opinions in other areas. She is extremely qualified and has reliable and relevant testimony in areas such as product development, design, risks, and testing, which Defendants attempt to lump in with her concessions. (*See* Def. Mem. at 4). Dr. Parisian is well-qualified to testify in the areas of product development, design, risks, and testing, and her testimony on those topics should be permitted by the Court.

Dr. Parisian has extensive qualifications in product development standards, having over 24 years in the research and development of medical devices, and in the development and use of voluntary industry standards—including the applicable recommendations of the Global Harmonization Task Force ("GHTF"). (Def. Ex. D at ¶ 1, 10, 14). Her opinions rely heavily on her training as to industry's use of voluntary industry standards to assist in development and

support of products. (*Id.* at ¶ 17). Even after leaving the FDA, Dr. Parisian continued to be an expert on industry standard committees and was involved with critique of those standards. (*Id.* at ¶ 18). Dr. Parisian is well qualified to perform risk assessments, having presided as a primary clinician assigned responsibility over 162 health risk assessments as a Medical Officer in the Office of Health Affairs while at the FDA. (*Id.* at ¶ 2, 3). Dr. Parisian relies on GHTF standards for her opinions in this case, which state, in relevant part, that a manufacturer should eliminate risk as reasonably practical through inherently safe design, by reducing as far as reasonably practicable the remaining risks by taking adequate protecting measures, and to inform users of residual risks. (*Id.* at ¶ 14. *See also*, Ex. B, GHTF Essential Principles of Safety and Performance of Medical Devices, Nov. 2, 2012, at 8-9).

Ethicon offers the traditional arguments against regulatory and industry standard experts: namely, that Dr. Parisian's testimony consists of narratives, legal conclusions, and that she lacks necessary qualifications and reliable methodology to do in this case what she has been doing for over 24 years. None of it is true. Dr. Parisian has fulfilled her obligation as an expert to state the facts and data supporting her opinions. FED. R. EVID. 702. This Court has already considered, and rejected, similar challenges to the qualifications of a regulatory expert in the *Bard* MDL. In the *Bard* MDL, Defendant C.R. Bard, Inc. ("Bard") challenged the design, testing and labeling opinions of the plaintiffs' expert, Dr. David A. Kessler, on the ground that he had no medical experience implanting pelvic mesh devices and was not an engineer or urogynecologist. In finding Dr. Kessler qualified to offer labeling and testing opinions, this Court aptly observed that a witness may be qualified by "knowledge, skill, experience, training or education." *In re Bard, Inc. Pelvic Repair System Litigation*, 2013 WL 2432918, *30-31 (S.D. W. Va., June 4, 2013), *citing*, FED. R. EVID. 702. Just as Dr. Kessler's work experience afforded him a working

knowledge of biomaterials that he discusses in the context of the regulatory process, Dr. Parisian's extensive professional experience affords her a general understanding of how medical issues interact with industry standards. It is that expertise that Dr. Parisian seeks to share with the jury.

When this Court was faced with similar criticisms of another industry standards expert by the Defendants in this MDL, it held that:

While it is true that Dr. Pence is not a doctor or biomedical engineer, she has more than forty years of experience in the research and development of pharmaceuticals and medical devices" and that when considering her additional role in presiding over a company that **"provides 'advice, guidance, and product development services to . . . medical device companies in the areas of strategic planning, preclinical testing, clinical trials design and conduct . . ."** that **"this experience is relevant to her opinion that Ethicon failed to act as a reasonably prudent manufacturer in testing the TVT, and she is therefore qualified to testify by her 'knowledge, skill, experience, training, or education[.]** Fed. R. Evid. 702.

In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig., 2014 WL 186872, at *30.

This Court has already considered, and rejected, the argument that specific, clinical expertise using a pelvic mesh device or practicing gynecology is a prerequisite to offering an opinion on the labeling of such a device. *Id.* at *29-32; *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 627-631. Instead, that issue should go to the weight of her opinions at trial. Similar to other regulatory experts who have testified, Dr. Parisian has over twenty years of experience in the drug and device regulatory field and over twenty-four years of experience in the research and development of medical devices. (Def. Ex. D at 6). Just as Drs. Kessler and Pence were deemed qualified in the various MDLs to offer expert industry standard of care opinions on the basis of their work for the FDA, Dr. Parisian is similarly qualified based on her experience.

Defendants assert that the district court's rulings in *Rheinfrank v. Abbott Labs.*, Case No. 13-cv-144-SJD (S.D. Ohio), Order Ruling on *Daubert* Motions (ECF No. 298), at 16-17,

Defendants' Exhibit C, supports their argument that Dr. Parisian is not qualified to offer opinions on scientific topics such as product development, risks, testing, marketing, and surveillance/studies, (again, Plaintiffs have conceded that Dr. Parisian is not offering any opinions regarding medical causation in this case) focusing on a single section of the opinion that states Dr. Parisian is not remitted to testify that Depakote was known to be the most teratogenic drug as of 2003, finding that Dr. Parisian does not have any specialized understanding or experience with regard to epileptic drugs. This is an extremely narrow ruling which entirely irrelevant to the analysis of Dr. Parisian's opinions in this case, as she not offered any such opinion regarding the two products in this case, the TVT-S and the Prolift +M. (e.g., Dr. Parisian has not offered no opinion that the Prolift +M or the TVT-S is the "most dangerous sling or mesh kit" or "the most likely to cause an erosion or other injury").

Moreover, the District Court's ruling in *Rheinfrank* actually support Dr. Parisian's qualifications and ability to offer opinions regarding scientific topics such as product development, risks, testing, marketing, and surveillance/studies, stating:

The Court, heeding the well-reasoned analysis of other courts determining whether Dr. Parisian is a qualified expert, finds that Dr. Parisian is well-qualified based on her experience, particularly her time spent as a Medical Officer for the FDA, to offer testimony about regulatory requirements relating to the **development, testing, marketing, and surveillance** of prescription drugs. *See Reece v. Astrazeneca Pharm., L.P.*, 500 F. Supp. 2d 736, 744 (S.D. Ohio 2007) (finding Dr. Parisian qualified to testify as to regulations governing the approval, labeling, advertising, and marketing of pharmaceutical and medical products, processes by which the FDA determines the **efficacy and safety** of new drugs and new drug applications, the issues the FDA considers in the development of product labeling and marketing information, and a manufacturer's responsibility within this system); *In re Gadolinium-Based Contrast Agents Prod. Liab. Lit.*, 2010 WL 1796334, at *13 (finding Dr. Parisian qualified to testify about regulatory requirements relating to **development, testing, marketing, and surveillance** of prescription drugs); *In re Fosamax Prod. Liab. Litig.*, 645 F. Supp. 2d 164, 191 (S.D. N.Y. 2009) (same).

Id. at 15-16 (emphasis added). Thus, the district court's ruling in *Rheinfrank* actually bolsters the legal precedent and support for Dr. Parisian to offer for the opinions she intends to give in this case, as the court confirms that she is well qualified and permitted in those areas, and only struck a single opinion regarding whether it was known that a specific drug was known to be the most dangerous one in its class at a specific point in time, which is not an opinion she has offered regarding the TVT-S or Prolift +M.

Not only does Dr. Parisian's extensive experience qualify her to opine on regulatory and industry standard of care issues, this Court has previously held such opinions as to the appropriateness of premarket testing are admissible where a regulatory expert relies on studies and international standards. *See Mathison v. Boston Sci. Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *15 (S.D. W. Va. May 6, 2015); *Sanchez v. Boston Sci. Corp.*, No. 2:12-CV-05762, 2014 WL 4851989, at *34 (S.D. W. Va. Sept. 29, 2014), *reconsideration denied*, No. 2:12-CV-05762, 2014 WL 5320559 (S.D. W. Va. Oct. 17, 2014). Here, Dr. Parisian incorporates a multitude of international standards, including GHTF standards, NICE recommendations, and the HAS study. (Def. Ex. D at 10; *Id.* at p. 44). Accordingly, the Court should not stray from its previous rulings and should deny Defendants' motion to exclude Dr. Parisian and allow her to testify regarding industry standards with regard to product development, design, risks, and testing of the Prolift+M and TVT-Secur as laid out in her expert reports. (*See Generally*, Def. Ex. D & E).

II. Defendants' Intent, Motive and "Narrative" Arguments Lack Merit.

Ethicon seeks to exclude Dr. Parisian's testimony, to the extent that it constitutes a narrative of documents or an expression of corporate intent, motive, state of mind, or amounts to legal conclusions. (Def. Mem. at 5-6, 6-8). Plaintiffs will comply with this Court's prior rulings

and will not elicit testimony from Dr. Parisian on Defendants' state of mind, motive, or intent. However, much of the testimony Defendants label as "state of mind" is merely a description of Ethicon's code of conduct, relevant industry standards, and Dr. Parisian's opinion that Ethicon failed to comply with these standards. These opinions do not delve into "state of mind" testimony that the Court has previously precluded, and are instead helpful to the jury by informing jurors as to the relevant industry and regulatory standards. Whether Ethicon failed to comply with its code of conduct or industry standards is not, as Ethicon asserts, knowledge or state of mind testimony, but rather information that will help a jury to determine whether Ethicon was negligent, and whether it produced an unreasonably dangerous product. Similarly, whether, how, and when Ethicon communicated safety information to physicians and patients goes to the heart of Plaintiffs' failure-to-warn claims.

The opinions offered are, thus, both relevant and helpful, as Dr. Parisian's expertise on regulatory and industry standards aids the jury in determining whether Defendants breached their duty to the Plaintiffs. Moreover, this Court rejected a similar argument that Ethicon advanced in *Lewis* with respect to "narrative" testimony. *In re Ethicon Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327, 2014 WL 186872, at *21 (S.D. W. Va. Jan. 15, 2014). In *Lewis*, Ethicon argued that Dr. Bruce Rosenzweig's testimony was inadmissible because "much of Dr. Rosenzweig's expert report is a summary of company documents, exhibits, and websites." *Id.* This Court rejected that argument, ruling that reliance on those materials "is helpful to the jury [in] understand[ing] the plaintiffs' . . . claims." Similarly, in *Cisson* this Court allowed an expert to offer factual narrative testimony "to the extent that [the narratives] may present the bases for the[] expert opinions." *Cisson v. Bard, Inc.*, 948 F. Supp. 2d 589, 646 (S.D. W. Va. 2013). Likewise, the court in *Smith v. Pfizer* rejected this exact argument, holding "[Plaintiff's expert]

may properly testify as to his interpretation of internal marketing-related documents that he relied on in forming his opinions.” *Smith v. Pfizer*, 714 F. Supp. 2d 845, 857 (M.D. Tenn. 2010). The same result is warranted here.

Dr. Parisian’s proffered testimony is not an impermissible narrative, but rather is proper testimony for the jury that is precisely within her realm of expertise. Other courts have determined that an expert may properly testify about, or comment upon, any document or exhibits in evidence, and may explain “the regulatory context in which they were created, defining any complex or specialized terminology or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge.” *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009). Thus, the factual materials considered by Dr. Parisian are not intended to be the subject of her testimony in and of themselves. Rather, the documents, evidence and factual matters referenced form the basis of her opinion and are relevant and helpful to the jury in explaining the regulatory context in which they were created. This testimony illustrates the considerations that are relevant at different stages of the regulatory process, and it allows Dr. Parisian to apply her expertise to draw inferences that would not otherwise be apparent to the jury. The use of factual materials in this way does not violate the rule against factual narratives. *See Id.*

Further, the “appropriate solution” is not to “parse the expert’s report;” but, rather, to trust that plaintiffs’ counsel will only present the facts necessary to the expert’s opinion and that the Court will be able to cut off lengthy factual narratives (if any) at trial. *In re C.R. Bard*, 948 F. Supp. 2d at 645-646. Thus, if Defendants truly believe that there is a lack of connection between the facts and Dr. Parisian’s expert opinions, the better time to object to narrative testimony is at trial. *Staub v. Breg, Inc.*, 2012 WL 1078335, at *3 (D. Ariz. March 30, 2012).

III. Dr. Parisian Is Qualified To Opine On Warnings For the Prolift+M and the TVT-S, including whether they were inaccurate or inadequate.

This Court has previously ruled that Dr. Parisian is qualified to testify about product warnings. *In re: Ethicon Inc.*, 2016 WL 4608165, at *3. However, the court also interpreted an argument by Plaintiffs, stating that Dr. Parisian's testimony will focus on whether the IFUs are **accurate**, as a concession that Dr. Parisian will not offer expert testimony about whether the relevant IFUs are **adequate**. *Id.* Plaintiffs did not intend to make such a concession, and Dr. Parisian does, in fact, offer opinions that the TVT-Secur and Prolift+M IFUs and patient brochures are inadequate (in addition to inaccurate), according to the applicable regulatory and industry standards. (Def. Ex. D at 31, 198 Def. Ex. F at 86, 99, 111). This Court has found that considering medical and scientific literature, the relevant IFUs, and internal Ethicon documents is a sufficient source of documents for an expert (Dr. Pence) to offer testimony about the adequacy of the relevant instructions for use. *In re: Ethicon Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2016 WL 4493655 (S.D. W. Va. Aug. 25, 2016). Dr. Parisian has examined this same collection of documents, as well as public information including FDA's documents, global industry standards, issues from similar products, and Ethicon employee testimonies. (Def. Ex. D at ¶ 13, Def. Ex. E at ¶ 13). Moreover, Dr. Parisian has been found to be qualified to testify as to the adequacy of a manufacturer's product warnings in the past. *Rheinfrank*, at 15, (finding that Dr. Parisian could testify that a drug manufacturer did not adequately communicate safety risks to healthcare providers, and that Dr. Parisian may opine as to what actions a drug manufacturer could have taken and/or was required to take with respect to communicating risks to healthcare professionals). As Dr. Parisian is qualified to offer opinions regarding the adequacy of the relevant IFUs, and she has employed a reliable methodology, her opinions on this topic should be permitted by the court.

Medical device manufacturers have an obligation to ensure that their labeling is, and remains, adequate over the lifecycles of their products. This issue is the heart of a failure to warn claim. As the product was introduced and remained on the market, a central question is whether Ethicon's Instructions for Use ("IFU") adequately informed physicians of known or knowable safety risks, so that surgeons and patients could make informed decisions. Federal regulations require medical device companies to report and analyze safety information as it is received, while a product remains on the market. *See, e.g.*, 21 C.F.R. § 803.50(a). Industry standards require that residual risk be communicated to end users. (Ex. B, GHTF Essential Principles of Safety and Performance of Medical Devices, Nov. 2, 2012., at 8-9).

Defendants attack Dr. Parisian's qualifications to testify and opine upon warnings, arguing that Dr. Parisian lacks the experience and qualifications to form her opinions. Defendants' first argument is meritless, and their second argument is incorrect. *See, e.g., Keffer v. Wyeth*, 791 F. Supp. 2d 539, 545 (S.D. W. Va. 2011) (denying summary judgment on the basis of Dr. Parisian's testimony as to warnings). Defendants' criticism of Dr. Parisian's qualifications centers almost exclusively on her lack of previous involvement with the specific devices at issue, either drafting patient brochures or IFUs for the devices at issue, or treating patients specifically for mesh products. (Def. Mot. at 9-10). These objections are unavailing, as this Court has previously held that treatment of patients is not a prerequisite for *Daubert* admissibility. *See In re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, 2014 WL 186872, at *30. Here, although Dr. Parisian has not drafted an IFU for the Prolift+M, Dr. Parisian has drafted IFUs for other medical devices as her testimony demonstrates:

Q. Did you help create an IFU?

A. For the investigators, yes, sir.

(Def. Ex. F; Deposition of Dr. Suzanne Parisian, March 8, 2016 at 54:2-3).

Similarly, Dr. Parisian has experience with patient brochures:

Q. Have you ever drafted a patient brochure for a surgically implantable device?

A. At the FDA I commented on them in terms of surgically implantable devices. I have not drafted it from square on. But in terms of medical devices, you're often more interactive with companies in terms of – like, I know I was involved with implantable cardiac defibrillators when they first came out and also some of the – so those would have been issues that I was looking at the labels, but I didn't draft them.

(Def. Ex. F at 56:5-15).

Defendants' argument is predicated on the assumption that an expert must have been directly involved in drafting IFU's or patient brochures for the *exact device* at issue in order to pass *Daubert*. Such an assumption has no support in the law, and this Court has previously found regulatory experts *qualified* to render similar testimony in the absence of direct involvement with product specific IFUs and patient brochures. *See Winebarger*, 2015 WL 1887222, at *18 (finding regulatory expert qualified to testify on opinions offered in expert report which included IFUs and patient brochures).² Rather, the fact that she has not drafted an IFU for these specific devices goes towards the weight of her testimony at trial, not the admissibility. Further, as set forth above, Dr. Parisian testified in the *Barba* trial with respect to Boston Scientific's IFU's, even though she had never crafted an IFU for the two devices at issue in that case. (Ex. 1, Trial Trans. (5/18/2015) at 21:4-23:12; 26:11-98:17). Dr. Parisian's extensive experience drafting or commenting upon IFU's and patient brochures renders her sufficiently qualified to testify as to her opinions.

² The Court did exclude some of Dr. Pence's opinions as unreliable, however no opinions were excluded on the basis of qualification. *Winebarger*, 2015 WL 1887222, at *20

Similarly, the fact that Dr. Parisian has no experience for treating women for SUI does not disqualify her from being able to opine about the sufficiency of Ethicon's warnings. Ethicon argues that this lack of knowledge renders her unqualified to opine on warnings; however, this lack of treating experience is not grounds for exclusion. This Court has held that "[a]n expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert*, so long as the expert has other 'sufficient facts or data' to support her opinion. *Mathison v. Boston Sci. Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *18 (S.D. W. Va. May 6, 2015). Here, Dr. Parisian's opinions are predicated on sufficient facts and data to render her opinions reliable and the criticisms offered by Ethicon are better reserved for cross examination at trial. *Id.*

Dr. Parisian's opinions revolve around regulatory expertise and industry standards. Because Dr. Parisian's opinion here centers upon the accuracy of the product label, Defendants' arguments related to adequacy of the methodology are misplaced and irrelevant. Dr. Parisian should be allowed to testify that Ethicon's communication of safety risks to physicians was inadequate, and to opine as to what actions Ethicon could have taken and/or was required to take with respect to communicating risks to doctors.

IV. Dr. Parisian Is Qualified To Opine Upon Foreign Regulatory Matters And This Testimony Will Be Helpful To The Jury.

Ethicon argues that Dr. Parisian is not qualified to opine on foreign regulatory matters because she has only a "'working familiarity' with 'international standards and requirements.'" (Def. Mot. at 10). However, Dr. Parisian explains in detail her unique qualifications to opine on foreign regulatory matters, including practical application of global industry standards. (Def. Ex. D at ¶ 18). These experiences include presentations to foreign medical associations, as well as "helping regulated industry obtain acceptance and reimbursement by foreign regulatory

agencies.” *Id.* Not only does Dr. Parisian have practical working experience in this field, but she provides a detailed explanation of her methodology on this point. *Id.* Although she may not be qualified to opine on the “laws” of foreign countries, her report and testimony indicate that her opinions do not delve into such matters, but are instead limited to global *regulatory standards*, on which she is qualified. Dr. Parisian’s considerable experience renders her qualified to offer these opinions.

Dr. Parisian’s opinions on international regulatory standards are similarly helpful to the jury. This Court has previously held that opinions on such standards are admissible. *See Mathison v. Boston Sci. Corp.*, No. 2:13-CV-05851, 2015 WL 2124991, at *15 (S.D. W. Va. May 6, 2015) (“GHTF standards, on the other hand, do not carry the same prejudicial force—the government does not promulgate them, manufacturers are not bound by them, and jurors are not familiar with them. And although the FDA appears to have had a limited role in the activities of the GHTF that role was not instrumental or definitive, and the work of the GHTF can be described without reference to the FDA.”) (internal citations omitted). Further, the Court found that such reliance on international standards was both reliable and helpful to the jury where a regulatory expert opined on such matters as premarket testing and some product labeling matters. *Id.* at *15. Because Dr. Parisian’s reliance on international standards is both reliable and helpful, her opinions should not be excluded *per se* simply because she incorporates international standards within her methodology. The court should again reserve ruling on these issues as it did previously. *In re: Ethicon Inc.*, 2016 WL 4608165, at *4.

VI. Dr. Parisian will not opine as to any product if she has not prepared an expert report for that Product

Dr. Parisian has prepared a report for the TVT-S and Prolift +M. While some of the cases in Exhibit A to Defendants’ motion involve products other than the TVT-S and Prolift +M, each of

the cases involves at least one of those two products. Dr. Parisian's opinions in those cases will be limited to the TVT-S and/or Prolift +M. Dr. Parisian has not issued any opinions regarding any other products at this time, and does not intend to offer any opinions regarding other products at this time.

CONCLUSION

For the reasons stated above, the Court should deny Defendants' motion and permit Dr. Parisian testimony to the extent stated in her reports. Dr. Parisian is an extremely well qualified and knowledgeable expert who has studied, developed and applied regulatory and industry standards to medical devices for over 20 years. Dr. Parisian can still offer her opinions even if evidence of FDA clearance and other FDA actions is excluded by this Court, as she relies on other standards in forming her opinions, including the GHTF guidelines and other industry standards. She should be permitted to give her opinions regarding the accuracy and adequacy of the IFUs and patient brochures, as well as the adequacy of product development, design, risks, and testing of the TVT-Secur and Prolift +M, according to industry standards.

Dated: April 27, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on April 27, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to CM/ECF participants registered to receive service in this case.

/s/ Thomas P. Cartmell

INDEX OF EXHIBITS

Exhibit A: Transcript of Dr. Parisian's May 18, 2015 testimony in the Barba trial.

Exhibit B: Final Document: Global Harmonization Task Force. Essential principles of Safety and Performance of Medical Devices, November 2, 2012 (revision of GHTF/SG1/N41:2005).